# Decision Memo for Air-Fluidized Beds for Pressure Ulcers (CAG-00017R)

## Decision Summary

In the absence of new clinical evidence that warrants a change, we will reaffirm the current national coverage policy on air-fluidized beds at this time. We are hopeful that our continued interest in the use of the most effective and appropriate support surfaces for Medicare patients with Stage III and Stage IV pressure ulcers who are being cared for in the non-institutional setting will stimulate scientific interest in this issue. Well-conceived and carefully carried out studies that show what subpopulation of patients clearly require and would benefit most from the use of an air-fluidized bed would be helpful to the Medicare program and the elderly and disabled population for whom it provides care.

We encourage the performance of studies comparing the clinical effectiveness of Group 2 support surfaces to that of air-fluidized beds in the treatment of Stage III and Stage IV pressure ulcers in the home setting. It would be particularly useful if the studies were designed with the characteristics of good clinical trials outlined above.

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## Decision Memo

To: File: CAG-00017R

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Re: Reconsideration of a National Coverage Decision on the Use of Air-Fluidized Beds

Date: February 19, 2002

On November 7, 2000 Hill-Rom, a manufacturer/supplier of air-fluidized beds, submitted three requests for modifications of the national coverage policy on air-fluidized beds for use in Stage III and Stage IV pressure ulcers to (1) add language to the decision in § 60-19 of the Coverage Issues Manual; (2) allow for exceptions to the requirement that conservative treatment be tried for one month and, more specifically, the required use of a Group 2 support surface for a full month, without any provision for physician discretion; and (3) leave to physician discretion whether or not a patient placed on an air-fluidized bed in the hospital, or in another facility, without the prior use of a Group 2 support surface for a 30-day period, can continue to use an air-fluidized bed when discharged home without first receiving a 30-day trial of conservative wound care, including the use of a Group 2 support surface.

Although Hill-Rom sent us three "Formal Request for a Modification," the existing mechanisms for members of the public to obtain national coverage are to submit a formal request for a national coverage decision or to submit a formal request for a reconsideration of an existing national coverage decision. Hill-Rom's requests most closely fit our description of a reconsideration, and we have treated them accordingly.

In our April 27, 1999 Federal Register Notice (64 FR 22619), we stated that we would not accept any new request for a reconsideration that did not include "additional medical and scientific information that we have not considered to make our original national coverage decision or an analysis of how we materially misinterpreted original information submitted by the requestor." For the substantive issues raised in all three requests, Hill-Rom did not submit additional material relevant to those issues that we had not previously considered nor did Hill-Rom state and specify that we materially misinterpreted original information. Therefore, Hill-Rom's three requests do not meet our criteria for reconsideration. However, we decided to address the company's second and third issues (described above) as an internally generated reconsideration. As part of this process, we took it upon ourselves to conduct a review and analysis of the relevant scientific literature and requested a technology assessment performed by an independent third party.

This memorandum serves four purposes: (1) outlines the use of support surfaces in the treatment of Stage III and Stage IV pressure ulcers; (2) reviews the history of Medicare coverage of air-fluidized beds for the treatment of Stage III and Stage IV pressure ulcers; (3) presents and analyzes the relevant clinical and scientific data related to the use of air-fluidized beds in comparison to Group 2 support surfaces; and (4) delineates the rationale for our decision to reaffirm the current national coverage policy.

**I. Clinical Background**

Pressure ulcers, also known as decubitus ulcers or bedsores, can be a common problem, particularly among the elderly, in acute care, nursing home, and home care populations. Other patient populations also at a high risk for these types of ulcers, include quadriplegic patients, patients admitted to the hospital for femoral fracture, and critical care patients. A pressure ulcer is any lesion caused by unrelieved pressure that results in damage to underlying tissue. Pressure ulcers occur when pressure or shear forces on the skin lead to occlusion of capillary blood flow and, ultimately, to skin cell death. The skin of an immobile bedridden patient, particularly over bony prominences, is more likely to be affected by pressure and shearing forces. Deep tissue necrosis and a loss of volume are characteristic of these ulcers. The most common areas for the development of pressure ulcers are on the buttocks (sacral areas), hips (iliac crest), knees, heels and ankles.[1]

Pressure ulcers are classified by the degree of tissue loss into four stages:

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| Stage I - | observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues. |
| Stage II- | partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater. |
| Stage III- | full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue. |
| Stage IV- | full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers. |

Originally we made the decision to cover use of air-fluidized beds in the home setting basedon information that the beds were useful in institutional settings to relieve pressure and treat Stage III and Stage IV pressure ulcers. It was thought that home use of air-fluidized beds may be an alternative to hospitalization for patients who have the support at home adequate to successfully use this bed. In 1995 we revised the policy to add several additional requirements including that "[a] trained adult caregiver is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage.[2] In an institutional setting professional nursing care is available around the clock for patients using these beds. However, in the home setting wound and other related care, such as toileting and repositioning, is often left to visiting home health nurses and caregivers.

Treatment of Pressure Ulcers

In developing a pressure ulcer treatment plan, it is customary to assess the entire body to include all areas potentially at risk for ulcer development. The type and extent of care for a particular ulcer depends on the ulcer stage. Standard wound care for pressure ulcers may include pressure relief by frequent repositioning, and use of a variety of support surfaces to reduce the pressure load on areas of the body at risk for new ulcer development and on areas where ulcers are already present.

A variety of support surfaces can be used to create an environment conducive to ulcer healing. A static support surface can be used if the patient can shift positions without placing weight on the pressure ulcer. A dynamic support surface can be used if an individual is unable to assume a variety of positions to relieve body weight on the site of a pressure ulcer. An air-fluidized bed using a flotation principal distributes weight evenly over the entire contact surface and has generally been used only with severe (Stage III or Stage IV) pressure ulcers. For Medicare purposes support surfaces have been divided into three groups of products. Group 1 support surface refers to a mattress overlay, such as a pressure pad for a mattress. Group 2 support surface describes a powered pressure reducing mattress, such as an alternating pressure or low air loss mattress. Group 3 support surfaces are air-fluidized beds.

An air-fluidized bed support system minimizes pressure over bony prominences through body "flotation" on fine ceramic beads that are set in motion by warm, pressurized air to simulate the movement of a fluid. The bed consists of a tank filled with silicone-coated microsphere beads. The beads resemble fine grains of sand. The tank is covered with a loose-fitting filter sheet that separates the patient from the beads. Room air is drawn into the base of the unit, then filtered, heated, and pushed into the tank through a diffuser board. The airflow suspends the beads causing them to take on the properties of a fluid. Usually the patient sinks 4-6 inches into the beads reducing the pressure put on the skin to below the capillary closing pressure. The warm air circulates around the patient and helps keep the patient warm and dry. The sheet is permeable to the warm air that fluidizes the beads and is permeable to the downward flow of body fluids such as wound drainage, urine and perspiration. As body fluids come in contact with the beads, the beads clump and drop to the bottom of the tank. The alkaline environment of the beads kills bacteria. The clumps are removed during routine maintenance. When the airflow is turned off, the beads settle into a mold around the body. Patient transfers in and out of the bed may be difficult and the head of most of these beds cannot be elevated.

**II. FDA Review**

Air-fluidized beds were approved for marketing by the FDA under the 510(k) clearance process to treat or prevent bedsores. The predicate device was the Rite-Hite electric hospital bed.

**III. History of Medicare Coverage of Air-Fluidized Beds**

Medicare has covered the home use of air-fluidized beds since July 30, 1990. The original policy was based largely on a 1989 Technology Assessment performed by the National Center for Health Services Research and Health Care Technology Assessment. Current provisions for Medicare coverage of air-fluidized beds are found in the Coverage Issues Manual § 60-19. The policy was last modified and effective November 1, 2000 to specify the components of conservative wound treatment to be employed before initiating use of an air-fluidized bed in the treatment of Stage III and Stage IV pressure ulcers.

Section 60-19 of the Coverage Issues Manual covers the use of air-fluidized beds only for the treatment of Stage III and Stage IV pressure sores that fail to show progressive healing with conservative treatment. Conservative treatment must have been provided for at least 30 days and includes the use of a Group 2 support surface. This requirement applies regardless of the setting in which the patient is treated. However, the use of an air-fluidized bed is not covered for home use under certain additional circumstances, such as when the patient has a coexisting pulmonary disease.

Hill-Rom, the requestor, asked CMS to reconsider the current national policy, in particular: (1) to allow for exceptions to the requirement of one month of conservative wound care, particularly the use of a Group 2 support surface, before using an air-fluidized bed; and (2) to allow physicians to determine if a patient on an air-fluidized bed in the hospital or other facility may continue using the bed when discharged home without first failing a course of treatment with a Group 2 support . As we stated in the Decision Memorandum posted on our website, we would review our policy with specific focus on a comparison between the clinical effectiveness of air-fluidized beds and Group 2 support surfaces, particularly in the home setting. To change our policy and cover the use of an air-fluidized bed as first line treatment in the home, the requestor should submit additional medical and scientific information, such as clinical studies of adequate quality to reliably demonstrate that air-fluidized beds are superior to or at least equally effective and safe as Group 2 support surfaces in treating Stage III or Stage IV pressure ulcers in the home setting. To change our policy to require less than 30 days of standard wound therapy including the use of a Group 2 support surface before using an air-fluidized bed, the requestor should submit additional medical and scientific information, such as clinical studies of adequate quality to reliably demonstrate that a specific amount of time less than 30 days of using standard wound care including a Group 2 support surface is sufficient to reliably determine that patients, or a subpopulation of patients, with a Stage III or Stage IV pressure ulcer will not experience progressive wound healing if such therapy is continued.

**IV. General Methodological Principles of Clinical Study Design**

CMS considers several generally accepted methodological principles when assessing a clinical trial. For example, we evaluate whether or not general methods of study design have been followed, such as calculating sample size *a priori*, specifying inclusion and exclusion criteria, describing the process for the selection of study participants and the ways in which the consistency of this process was maintained, ensuring comparability of experimental and control groups at baseline to the extent possible, describing baseline characteristics of the participants, randomizing study subjects, masking of patients and investigators to the therapy administered to the extent feasible, describing co-interventions in detail, and performing appropriate statistical analyses, such as statistical tests of differences in baseline characteristics between the comparison groups. CMS evaluates other study design issues, which, in the case of wound care trials, include, among other things, the following:

- Has an appropriate outcome been used? For example, the optimal outcome to measure is the number and proportion of wounds that reach complete closure. Assessing partial healing provides less assurance of clinical effectiveness, because the clinical benefit of partial healing has not been demonstrated.
- Have appropriate measures of endpoints been selected, identified prior to initiating the trial, and standardized across all study sites? Have clear measurement criteria been provided? Has the process used to measure the selected outcomes and methods in which the study investigators insured the consistency of this process across different study sites been described?
- Was the appropriate patient population studied? For example, was the study performed on patients with the wound type for which coverage is sought?
- Has a single reference wound been selected for each patient? Generally, including multiple wounds on a single patient in the analysis provides limited additional data of value, because individual wounds are not independent.
- Have all subjects, regardless of the protocol arm to which they are assigned (e.g., investigational treatment, control), received good standard care and the same standard care procedures? Have the standard care procedures been described in detail?
- Have variables that may affect results been addressed in the analysis, including surface area, depth, and chronicity of wounds, condition of the subject, age of the subject?
- Has the effect of the therapy under investigation on the wound been evaluated? Adverse effects on healing can manifest in several ways, including tissue necrosis requiring more debridement, erythema, and discharge.
- Have adequate follow-up evaluations been performed? Clinical benefits from wound therapies can be short-lived and, therefore, of limited clinical value.

The FDA has also issued guidance that may be useful to investigators.[4] In addition, numerous useful texts have been published on general trial design and evidence-based medicine review of studies.[5]

**V. Summary of Evidence**

In addition to the material submitted by the requestor, Technology Assessments from ECRI, Blue Cross Blue Shield, and the National Center for Health Services Research and Health Care Technology Assessment, and a Clinical Practice Guideline by the Agency for Healthcare Research and Quality (AHRQ, formerly the Agency for Health Care Policy and Research), we conducted a literature search to locate peer-reviewed medical literature assessing the effectiveness of air -fluidized beds in the treatment of Stage III and IV pressure ulcers in the home setting. We were particularly interested in comparisons of their effectiveness to Group 2 support surfaces, including powered pressure reducing air mattresses.

A 1994 AHRQ Guideline, *Treatment of Pressure Ulcers*, stated that "[i]f a patient has large Stage III or Stage IV pressure ulcers on multiple turning surfaces, a low-air-loss bed [a type of Group 2 support surface] or an air-fluidized bed may be indicated." The studies identified only pertained to use in the acute care setting and the strength of the evidence was rated as "C" (one controlled trial, at least two case series/descriptive studies, or expert opinion), the lowest rating. In addition, the Guideline states that "[n]o studies have compared the effectiveness of low-air-loss beds and air-fluidized beds. Unlike air-fluidized beds, low-air-loss beds can be raised and lowered, and the heads of these beds can be elevated. In addition, transferring patients in and out of bed is easier with low-air-loss than with air-fluidized beds.... A randomized controlled trial will be required to compare low-air loss bed and air-fluidized bed therapy." We are not aware of such a published study.

The AHRQ Guideline, which Hill-Rom cites, also states that "[a] clean pressure ulcer should show evidence of some healing within 2 to 4 weeks. If no progress can be demonstrated, reevaluate the adequacy of the overall treatment plan as well as adherence to this plan, making modifications as necessary." The evidence is rated as "C."

The van Rijswijk and Braden article cited by the requestor in support of using a course of conservative wound care of less than 30 days states "[r]eduction in wound size following 2 weeks of treating Stage III and IV pressure ulcers has been found to predict time to healing. Also, when Bates-Jensen examined data of 80 healed pressure ulcers (mostly Stage II and III), she found that the vast majority (76%) did show a reduction in ulcer size following 2 weeks of treatment. Finally, several prospective leg ulcer studies have shown that reduction in ulcer size after 2 to 4 weeks of treatment is independently predictive of time to healing and/or outcome."[8] The latter studies were primarily performed in patients with venous ulcers. Significantly, all these studies provided findings for a population of patients. While two weeks of treatment may be an adequate course for some patients to determine if that treatment will or will not work, the studies do not permit a reliable determination of which patients require 2 weeks, which require 3 weeks, or which require 4 weeks of treatment before an accurate conclusion can be drawn. Also, the authors conducted a review of articles published from 1993 to 1998 to update the AHRQ Guidelines. Based on their review, the authors did not suggest a modification to the original AHRQ recommendation regarding a 2 to 4 week treatment trial.

A 1998 Technology Assessment by the Blue Cross and Blue Shield Association concluded that: "The available data are insufficient to evaluate the health outcomes of treatment with air-fluidized therapy as compared to either treatment with a Group 1 or Group 2 pressure-reducing support surface in patients at risk of developing pressure ulcers or in patients with established pressure ulcers."

A second Technology Assessment has been performed by ECRI at our request, in November 2001, and found only one clinical study, by Strauss[9] in 1999, of air-fluidized beds used in the home setting. No published clinical trial other than that study compares the use of an air-fluidized bed with Group 2 support surfaces in a non-institutional setting.

Strauss was a randomized controlled trial of 112 patients with Stage III and Stage IV pressure ulcers that compared use of an air-fluidized bed to a variety of other support surfaces (both Group 1 and Group 2) in the home setting. The primary purpose of the study was not to compare wound healing between different surfaces, but to compare cost of care. The hypothesis was that the more expensive air-fluidized bed prevented hospital admissions for decubitus care and thus was not more expensive than conventional care utilizing other surfaces. Differences in clinical outcome, which were not described in detail, were assessed by review of serial photographs of some patients' wounds by independent nurses. The results were described as "not statistically significant". Only 59 (53 per cent) of patients completed the study, which followed patients through 36 weeks of wound treatment. There were significant differences in overall patient care between groups participating in the study. Patients assigned to the air-fluidized bed arm received weekly visits by a nurse for the first four weeks and biweekly visits, thereafter. If the nurse found that pressure ulcer(s) were not healing, the attending physician was contacted for recommendation of alternate or supplemental therapies to enhance wound care. Patients on other support surfaces, however, received biweekly visits for only the first four weeks and, thereafter, biweekly telephone calls. The nurse contacted these patients' attending physicians only in the event of an emergency. This difference in oversight and intensity of care during the study makes it different to draw conclusions about the impact of the support surface alone on wound healing. Further, the small numbers and variety of Group 1 and Group 2 support surfaces included in the study make it statistically difficult to perform valid comparisons of their efficacy relative to a Group 3 support surface.

ECRI also reviewed a 1987 study by Allman[10] on the use of air-fluidized beds for the care of hospitalized patients with pressure ulcers of all stages, including superficial wounds. Of 140 potentially eligible patients, 72 were enrolled and 65 completed the study (31 on the air-fluidized bed). These hospitalized patients were followed until death, discharge or wound healing (range 4 - 77 days), although the median follow-up was only 13 days. The control group (34 patients) used alternating air mattresses covered with a foam pad and received standardized nursing care that included repositioning every two hours. Patients on the air-fluidized bed were repositioned every four hours only on the day and evening nursing shifts. Healing was assessed by review of serial color photographs and wound surface area was measured by serial transparent tracings. The median surface area of wounds treated with the air-fluidized bed decreased 1.2 $cm^2$, whereas wound surface area for patients on the air mattresses increased by 0.5 $cm^2$ during the study. Nine patients on the air-fluidized bed and 8 on the air mattress achieved a 50% reduction in wound surface area. Of note the median surface area of patients randomized to the air-fluidized bed was 7.8$cm^2$ at the beginning of the study, about 25% smaller than the 10.8 $cm^2$ for those patients on the air mattresses. And, although the authors did not believe it significant, 25 of 34 patients on the air mattress were diabetic, while only 17 of the 31 patients on the air-fluidized bed were. While several of these differences in the two study groups could bias the outcome, the most glaring problem with this study is the inclusion of superficial ulcers, which the authors admit "were the ones most likely to achieve marked improvement." No attempt is made to identify the number of superficial ulcers in either group of patients and there is no information provided about differences in the stages of ulcers between the two study groups. Surface area is not an adequate measure of the severity of an ulcer, since stage assessment is primarily based on depth.

ECRI also analyzed a Cochrane Review of beds, mattresses and cushions for pressure ulcer prevention and treatment performed in 2001. Although the authors of the Review concluded that air-fluidized beds may improve pressure wound healing rates, the conclusion was based on only three studies, two of which were the Strauss and Allman studies cited above. The third study by Munro[11] in 1989 was also a study of institutional rather than home care, included a large proportion of Stage II ulcers and excluded Stage IV ulcers. Further this study did not describe the bed/mattress that was compared to the air-fluidized bed, did not describe the method of randomization used, and presented only mean ulcer sizes for comparison without documentation of the range of wound sizes. The authors of the Review cautioned that their confidence in their conclusion was tempered by the poor quality of the studies and the failure to replicate most comparisons.

ECRI could not conclude that a Group 3 support surface was superior to a Group 2 surface for the treatment of pressure ulcers in the home setting based of the literature it was able to locate for review.

**VI. CMS Analysis**

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

Given the variety of items and services that may be covered under the Medicare program and the medical needs of our beneficiaries, the most common method of determining whether the expenses related to items and services are "reasonable and necessary" is to conduct a fact-specific inquiry on a claim-by-claim basis. In deciding claims on this basis, the beneficiary bears the burden of proving entitlement. 42 C.F.R. § 424.5(a)(6) ("The provider, supplier, or beneficiary, as appropriate, must furnish sufficient information to determine whether payment is due and the amount of payment.") On some occasions, however, the medical and scientific evidence is sufficiently compelling that the agency is able to make a national determination as to whether or not the expenses related to a particular item or service are "reasonable and necessary" for a particular population of beneficiaries with the same salient characteristics. Because NCDs are binding on Medicare contractors and administrative law judges, they often serve to obviate the need for expensive and time-consuming claim-by-claim analysis.

We reviewed the available medical literature, including the material submitted by the requestor, and the new ECRI assessment, but we were unable to locate any studies of the use of air-fluidized beds other than the ones noted above, which were the basis of the ECRI assessment. No material was submitted by the public other than from the requestor.

The available evidence is not of adequate quality to reliably conclude that air-fluidized beds are clinically superior to any of the Group 2 support surfaces for the treatment of Stage III or Stage IV pressure ulcers in the home setting. At best the evidence we reviewed suggests that air-fluidized beds and Group 2 support surfaces have equal clinical effectiveness in the home setting, although we cannot conclude that they are equal based on existing clinical studies. In addition, transferring patients in and out of air-fluidized beds is difficult, particularly in the home where adequate staffing may not be available. Adverse events from using air-fluidized beds, such as corneal abrasion and dehydration, have been reported. Also, the literature on the subject is relatively old and cannot take into account any improvements in the manufacturing and design of Group 2 surfaces, such as improvements in durability and pump design, that have taken place in recent years. Finally, none of the evidence submitted was of adequate quality to support a shorter course of conservative treatment before using an air-fluidized bed. A 30-day course of conservative wound care is not inconsistent with the AHRQ Guidelines or the van Rijswijk and Braden article cited by the requestor.

We would encourage parties interested in this topic to undertake or complete studies which may currently be underway that will provide clear evidence of differences in health outcomes that might be attributed to superiority of a particular support surface. Such studies should show that purported benefits can be achieved in the home setting with its inherent limitations in provision of professional level nursing services as well as address potential adverse events that may occur from use of the item.

**DECISION**

In the absence of new clinical evidence that warrants a change, we will reaffirm the current national coverage policy on air-fluidized beds at this time. We are hopeful that our continued interest in the use of the most effective and appropriate support surfaces for Medicare patients with Stage III and Stage IV pressure ulcers who are being cared for in the non-institutional setting will stimulate scientific interest in this issue. Well-conceived and carefully carried out studies that show what subpopulation of patients clearly require and would benefit most from the use of an air-fluidized bed would be helpful to the Medicare program and the elderly and disabled population for whom it provides care.

We encourage the performance of studies comparing the clinical effectiveness of Group 2 support surfaces to that of air-fluidized beds in the treatment of Stage III and Stage IV pressure ulcers in the home setting. It would be particularly useful if the studies were designed with the characteristics of good clinical trials outlined above.

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1 `Silver FH, Wang MC, A review of the etiology and treatment of skin ulcers with wound dressings: comparison of the effects of occlusive and nonocclusive dressings. J. Long Term Eff Med Implants 1992;2(4):267-88.

2 *See also*, National Center for Health Services Research and Health Care Technology Assessment, DHHS, Public Health Service, *Guidelines for Home Air-Fluidized Bed Therapy, 1989*, which states that "adequate support should include trained caregivers to assist the patient in the managing and maintaining the system."

3 `Silver FH, Wang MC, A review of the etiology and treatment of skin ulcers with wound dressings: comparison of the effects of occlusive and nonocclusive dressings. J. Long Term Eff Med Implants 1992;2(4):267-88.

4 *FDA Guidance for Industry: Chronic Ulcer and Burn Wounds - Developing Products for Treatment* (June 2000).

5 For example, Egger M., Smith G.D., Altman DG (eds.), *Systematic Reviews in Health Care: Meta-Analysis in Context*. BMJ Publishing Group, 2001; Gray J.A.M., *Evidence-Based Healthcare: How to Make Health Policy and Management NCDs*. Churchill Livingstone, 1998; Mulrow C., Cook D. (eds.), *Systematic Reviews: Synthesis of Best Evidence for Health Care NCDs*. American College of Physicians, 1998.

6 *FDA Guidance for Industry: Chronic Ulcer and Burn Wounds - Developing Products for Treatment* (June 2000).

7 For example, Egger M., Smith G.D., Altman DG (eds.), *Systematic Reviews in Health Care: Meta-Analysis in Context*. BMJ Publishing Group, 2001; Gray J.A.M., *Evidence-Based Healthcare: How to Make Health Policy and Management NCDs*. Churchill Livingstone, 1998; Mulrow C., Cook D. (eds.), *Systematic Reviews: Synthesis of Best Evidence for Health Care NCDs*. American College of Physicians, 1998.

8 Van Rijswijk L, Braden B. Pressure ulcer patient and wound assessment: An AHCPR clinical practice guideline update. Ostomy/Wound Management 1999; 45(Suppl 1A):56S-67S.

9 Strauss MJ, Gong J, Gary BD, Kalsbeek WD, Spear S. The cost of home air-fluidized therapy for pressure sores. A randomized controlled trial. J Fam Pract 1991 Jul;33(1):52-9.

10 Allman RM, Walker JM, Hart MK, Laprade CA, Noel LB, Smith CR. Air-fluidized beds or conventional therapy for pressures sores. A randomized trial. Ann Intern Med 1987 Nov;107(5):641-8

11 Munro BH, Brown L, Heitman BB. Pressure ulcers:one bed or another? Geriatr Dermatol 1989 Jul-Aug; 10(4):190-2.

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